



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

10/616,692

Applicant

Nelson, Jodi

Filed

July 9, 2003

TC/A.U.

1614

Examiner

Unassigned

For

Compositions and Methods

For the Treatment of Parkinson's Disease and **Tardive Dyskinesias**

Docket No.

47-00B

Customer No.:

23713

Hon. Commissioner for Patents Mail Stop Amendment P.O. Box 1450 Alexandria, VA 22313-1450

Confirmation No. 1639

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage for Express Mail in an envelope addressed to:

Commissioner for Patents PO Box 1450, Alexandria, VA 22

December 12, 2005 Date

EV 693371921 US Express Mail Tracking Number

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Further to the Information Disclosure Statements filed August 24, 2005, June 10, 2005, June 27, 2005, and September 20, 2005, the Examiner is respectfully requested to consider the additional references, copies enclosed, which may qualify as prior art. For the Examiner's convenience, the references are listed on the attached Patent and Trademark Office Form PTO-1449.

References known to the applicants have been listed on the enclosed form PTO-1449 or a substitute. That information is cited in a spirit of forthrightness and cooperation to enable the applicants to obtain that measure of protection for the invention to which there is entitlement. However, no representation is made that the listed art actually qualifies as prior art under the patent statute and the mere use of form PTO-1449 or a substitute is not an admission that all listed references are prior art. No representation is made that applicants know of the best art.

It is believed this submission does not require the payment of any fees; however, if this is incorrect, please credit any overpayment or deduct any additional fees due from deposit account no. 07-1969, including fees for additional extensions of time which may be required.

Respectfully submitted,

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Sheet 1 of 2

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B	Application Number	10/616,692
	Filing Date	09/07/2003
INFORMATION DISCLOSURE	First Named Inventor	Nelson
TATEMENT BY APPLICANT	Art Unit	1614
17E	Examiner Name	Unassigned
	Attorney Docket Number	47-00B

GWS 12/12/2005

U.S. PATENT DOCUMENTS

Examiner Initial*	Cite No.1	Document Number (US-)	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)
	1	5,496,836	03/05/1996	Di Rocco et al.	
	2	5,352,688	10/04/1994	Kaminski	

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No. ¹	Foreign Patent Document Number (include WIPO country code)	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)	T ²

NON-PATENT LITERATURE DOCUMENTS

Examiner Initial*	Cite No. ¹	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3	ABIOSE, A.K., et al., Chloroquine-induced venodilation in human hand veins; Clinical <i>Pharmacology & Therapeutics</i> , June 1997, Vol. 61, No. 6, 677-683.	
	4	ADLER, L.E., et al., Cimetidine Toxicity Manifested as Paranoia and Hallucinations; Am J Psychiatry, Sept. 1980, 137:9, 1112-1113.	
	5	BATEMAN, D. N., et al., Cimetidine induced postural and action tremor; <i>J Neurol Neurosurg Psychiatry</i> , Jan. 1981, 44(1):94.	
	6	AMABEOKU, G. J., Some behavioural effects of chloroquine in rats suggesting dopaminergic activation; <i>Indian J Med Res.</i> , Feb. 1994, 99:87-94.	
	7	BYRON, J. W., Mechanism for Histamine H₂-Receptor Induced Cell-Cycle Changes in the Bone Marrow Stem Cell; <i>Agents & Actions</i> , Jul. 1977, 7(2):209-13.	
	8	DONATELLI, P., et al., Stereoselective inhibition by chloroquine of histamine N-methyltransferase in the human liver and brain; <i>Eur J Clin Pharmacol.</i> , 1994, 47(4):345-9, abstract only.	
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	10	GARCIA-RUIZ, P.J., et al., Cinnarizine-induced parkinsonism in primates; <i>Clinical Neuropharmacology</i> , Apr 1992, 15(2):152-4, abstract only.	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here or "x" if English language Translation is attached.

DEC 1 2 2005

Sheet 2 of 2

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B	Application Number	10/616,692
	Filing Date	09/07/2003
INFORMATION DISCLOSURE	First Named Inventor	Nelson
STATEMENT BY APPLICANT	Art Unit	1614
	Examiner Name	Unassigned
	Attorney Docket Number	47-00B

GWS 12/12/2005

		REFERENCE	_ ,
Examiner Initial*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
:	11	GARCIA-RUIZ, P.J., et al., Parkinsonism associated with calcium channel blockers: a	
		prospective follow-up study, <i>Clinical Neuropharmacology</i> , Feb. 1992, 15(1);19-26, abstract only.	
	12	HANDLER, C. E., et al., Extrapyramidal and cerebellar syndrome with encephalopathy associated with cimetidine; <i>Postgrad Med Journal</i> , Aug. 1982, 58:527-528.	
	13	HARLE, D.G., et al., Structural features of potent inhibitors of rat kidney histamine N-methyltransferase; <i>Biochem Pharmacol.</i> , Feb. 1988, 37(3):385-8, abstract only.	
	14	HUTCHISON, T. A., et al., Comparative Dosage Table – Histamine H2 Receptors; Drugdex® System, 2000.	
	15	KUSHNER, M. J., Chorea and Cimetidine; <i>Annals of Internal Medicine</i> , Jan. 1982, 96(1):126.	
	16	KUZUHARA, S., et al., Parkinsonism, depression and akathisia induced by flunarizine, a calcium entry blockade – report of 31 cases; <i>Shinkeigaku (Japan)</i> , June 1989, 29(6):681-6, abstract only.	
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	18	LOT, T. Y., The effects of chronic administration of chloroquine and quinacrine on the response of normal and denervated smooth muscle to agonist drugs; <i>Physiol Behav.</i> , Aug. 1993, 54(2):345-9, abstract only.	
	19	McMAHON, T., Dyskinesia associated with amoxapine withdrawal and use of carbamazepine and antihistamines; <i>Psychosomatics</i> , Feb. 1986, 27(2):145-148.	
	20	NEGROTTI, A., et al., Calcium-entry blockers-induced parkinsonism: possible role of inherited susceptibility, <i>Neurotoxicology</i> , Spring 1992, 13(1):261-264, abstract only.	
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	22	PORTER, J. B., et al., Intensive Hospital Monitoring Study of Intravenous Cimetidine, Arch Intern Med, Nov. 1986, 146:2237-9.	
	23	TAKAHASHI, A., et al., Drug-induced movement disorders; <i>Nippon rinsho (Japan)</i> , Nov. 1993, 51(11):2929-34, abstract only.	
	24	TOTTE, J., et al., Neurological Dysfunction Associated with Abnormal Levels of Cimetidine Metabolite, <i>The Lancet</i> , May 1981, 1(8228):1047.	
	25	Micro Medex website, DRUGDEX® Drug Point, Drug Point® Summary, FAMOTIDINE, printout Dec. 2005	
	26	Micro Medex website, CIME Adult Dosages, printout Dec. 2005	
~	27	Micro Medex website, CQ Precautions, printout Dec. 2005	<u> </u>
	28	Micro Medex website, CIME – Neurological AEs, printout Dec. 2005	<u> </u>

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

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Nelson

Serial No.:

10/616,692

Filing Date: Title:

07/09/2003

Composites and Methods for the Treatment of

Parkinson's Disease and Tardive Dyskinesias

I hereby certify that the following correspondence, along with any other document referenced to as being attached or enclosed:

1. Substitute for PTO Form 1449 – 2 pages

- 2. Supplemental Information Disclosure Statement 2 pages
- 3. Copy of 28 references
- 4. Certificate of Mailing by Express Mail (37 CFR 1.10) 1 page
- 5. Return Postcard

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